K003478

FEB - 5 2001

zimmer

P.O. Box 708
Warsaw, IN 46581-0708
219 267-6131

Summary of Safety and Effectiveness

- **Submitted By:**

  Zimmer, Inc.
  P.O. Box 708
  Warsaw, Indiana 46581-0708
  219-267-6131

- **Contact Person:**

  Karen Cain
  Senior Regulatory Affairs Associate
  Telephone: 219/372-4219
  Telefax: 219/372-4605

- **Date:**

  November 7, 2000

- **Trade Name:**

  Trilogy® Acetabular System, 46 mm Large Head Liners

- **Common Name:**

  Polyethylene Acetabular Liners

- **Classification Name:**

  Hip Joint Metal/Polymer/Metal Semiconstrained Porous-Coated Uncemented Prosthesis

- **Predicate Devices:**

  - Inter-Op DURASUL Acetabular Insert, manufactured by Sulzer Orthopedics, Inc., K993259, cleared March 10, 2000

  - *Trilogy* Acetabular System, manufactured by Zimmer, Inc., K934765, cleared April 29, 1994

- *Trilogy* Acetabular System, *Longevity*® Crosslinked Polyethylene Liners, manufactured by Zimmer, Inc., K990135, cleared July 12, 1999

- *Trilogy* Acetabular System, 7 mm Offset, manufactured by Zimmer, Inc., K954698, cleared January 17, 1996

- *Trilogy*® Acetabular System Large Head Liners, manufactured by Zimmer, Inc., K002960, currently pending review at FDA.

- **Device Description**

The *Trilogy* 46 mm Large Head Liners are acetabular shell liners manufactured from ultra-high molecular-weight polyethylene (UHMWPE). The 46 mm Large Head Liners are used in conjunction with currently marketed *Trilogy* Acetabular Shells and serve as the articular surface of the acetabular component in total hip replacement. These liners feature a 10-degree elevated rim and oversized inner diameters to provide increased range of motion and stability to the hip joint of a patient.

Wear testing and locking mechanism integrity evaluations all indicated that this line addition would perform as intended and similar to legally marketed devices. The results of *in vitro* wear tests have not been shown to correlate with clinical wear mechanisms.

- **Intended Use**

The *Trilogy* 46 mm Large Head Liners are intended for use with the *Trilogy* Acetabular System Shells in cemented or noncemented use in skeletally mature individuals undergoing primary or revision surgery for rehabilitating hips damaged as a result of noninflammatory degenerative joint disease (NIDJD) or its composite diagnoses of osteoarthritis, avascular necrosis, protrusio acetabuli, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

- **Comparison to Predicate Devices**

The *Trilogy* 46 mm Large Head Liners are substantially equivalent to the above named devices in that all are intended to replace the bearing surface of the acetabulum. All predicate devices, as well as the *Trilogy* 46 mm Large Head Liners, are manufactured from UHMWPE and are intended for cemented or cementless use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Karen Cain
Senior Regulatory Affairs Associate
Zimmer, Inc.
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K003478
Trade Name: Trilogy® Acetabular System, 46mm Large Head Liners
Regulatory Class: II
Product Code: LPH
Dated: November 7, 2000
Received: November 9, 2000

Dear Ms. Cain:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit H

510(k) Number (if known) K003478

Device Name:

Trilogy® Acetabular System, 46 mm Large Head Liners

Indications for Use:

The *Trilogy* Acetabular System is indicated for either cemented or noncemented use in skeletally mature individuals undergoing primary or revision surgery for rehabilitating hips damaged as a result of noninflammatory degenerative joint disease (NIDJD) or its composite diagnoses of osteoarthritis, avascular necrosis, protrusio acetabuli, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use
(Optional Format 1-2-96)

for Mark N Milhauser
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K003478

RA10002K.510